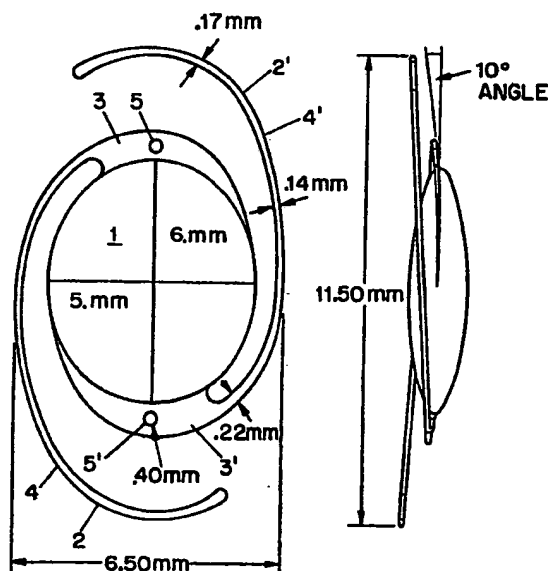


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61F 2/16	A1	(11) International Publication Number: WO 92/15260 (43) International Publication Date: 17 September 1992 (17.09.92)
<p>(21) International Application Number: PCT/EP92/00449</p> <p>(22) International Filing Date: 2 March 1992 (02.03.92)</p> <p>(30) Priority data: 663,581 1 March 1991 (01.03.91) US</p> <p>(71)(72) Applicant and Inventor: ARNOTT, Eric, J. [GB/GB]; Trottsford Farm, Headly, Near Bordon, Hampshire GU35 8TF (GB).</p> <p>(74) Agent: LUCAS, Brian, Ronald; Lucas & Co., 135 Westhall Road, Warlingham, Surrey CR6 9HJ (GB).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), BR, CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, KP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).</p>		<p>Published <i>With international search report.</i></p>

(54) Title: INTRAOCULAR LENS WITH TAPERED HOLDING LOOPS**(57) Abstract**

An intraocular lens for insertion in the posterior chamber of a human following removal of a cataract comprising: a) an optic (1); and b) first and second similar holding loops (2, 2') generally symmetrically disposed about the optic, said holding loops each comprising a free loop portion (4, 4') which when compressed in the posterior chamber together form a substantially encircling ring around the optic, wherein the free loop portions are tapered to a minimum radial thickness at at least one selected point to maximize contact between the free loop portions and the interior surface of the posterior chamber when compressed.

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15 INTRAOCULAR LENS WITH TAPERED HOLDING LOOPS

of which the following is a

SPECIFICATION

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BACKGROUND OF THE INVENTION

25 This application relates to a posterior chamber intraocular lens having totally encircling holding loops which have been selectively tapered to increase the extent of contact between the holding loops and the interior structure of the posterior chamber, e.g. the capsular bag.

30 Intraocular lenses (IOLs) are the current prostheses of choice to restore vision to persons suffering from clouding of the natural lens due to cataracts. Such lenses are implanted by an ophthalmic surgeon in the eye of the patient after the clouded natural lens has been removed. In general, the lens is
35 placed either anterior to the pupillary opening in what

is called the anterior chamber, or posterior to the pupillary opening in what is called the posterior chamber. A preferred technique utilized when a posterior chamber lens is to be implanted involves
5 implantation of the lens in the structure known as the capsular bag, which is a very thin membrane which surrounds the natural lens and which can be preserved in part through a surgical procedure called extracapsular extraction.

10 Intraocular lens designs encompass a wide variety of shapes and sizes depending on the surgical technique used, the intended placement of the lens in the eye and the preference of the surgeon. One successful group of such lenses are the totally encircling loops lenses such
15 as those disclosed in my prior U.S. Patent No. Re 33,039, which is incorporated herein by reference.

As shown in Fig. 1, one embodiment of a totally encircling loop lens is formed from a central optic portion 1 and two similar holding loops or haptics 2 and
20 2'. The holding loops have a thin elongated portion 4 and 4' which is referred to as the free loop portion and may also include a gusset or base portion 3 and 3' between the optic and the proximal and of the free loop portion. Once implanted in the eye, the free loop
25 portions of the lens are compressed to form a ring around the optic when viewed from above the optic. As explained in U.S. Reissue No. 33,039 this ring provides a barrier to fibrous or cellular ingrowth, sometimes referred to as Elschnigs Pearls, thus retarding clouding
30 of the replacement lens which sometimes occurs after surgery. The ring also provides a supporting structure within the posterior chamber and specifically in the capsular bag for the vitreous and fibrosis around the free loop portions fixed within the capsular bag gives
35 greater stability to the entire implant.

SUMMARY OF THE INVENTION

5 The present invention provides an improvement to
the totally encircling loop posterior chamber lenses
previously known. In the lenses of the invention,
contact between the compressed free loop portions of the
implant and the interior of the posterior chamber is
increased so as to improve both the barrier and support
10 functions of the holding loops. This improved contact
is achieved by varying the radial thickness of the free
loop portion throughout its length to cause the shape of
the compressed free loop portions to conform to the
structure of the eye in which the implant is housed.
15 Thus, the improved lens of the invention comprises an
optic and two substantially similar holding loops
symmetrically or substantially symmetrically disposed
about the optic. Each of said holding loops includes a
free loop portion that is tapered to have a minimum
20 thickness at least at one point between the proximal and
distal ends of the free loop to bring about increased
contact between the free loop portion and the
surrounding structure, e.g. capsular bag.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a totally encircling loop IOL in
accordance with the U.S. Reissue 33,039;

30 Fig. 2 shows a totally encircling loop IOL in
accordance with the prior art within the capsular bag;

Fig. 3 shows a totally encircling loop IOL in
accordance with the prior art within the capsular bag;

Fig. 4 shows an IOL with tapered holding loops in
accordance with the invention;

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Fig. 5 shows an IOL with tapered holding loops in

accordance with the invention;

Fig. 6 shows an IOL with tapered holding loops in accordance with the invention;

Fig. 7 shows an IOL with tapered holding loops in accordance with the invention;

Fig. 8 shows an IOL with tapered holding loops in accordance with the invention;

Fig. 9 shows an IOL with tapered holding loops in accordance with the invention; and

Fig. 10 shows an IOL with tapered holding loops in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 2 is a representation of a totally encircling loop lens within the capsular bag 21 with holding loops having a substantially uniform thickness, i.e., not selectively tapered segments in the free loop portion. The darker line represents the shape of the lens in its uncompressed position while the white line shows the lens as compressed. As can be seen from this figure, while there is a ring completely around the optic portion of the implant, only about a third of the free loop portion is actually in contact with the periphery (fornix) of the capsular bag 21. This same effect is seen with other totally encircling lenses without the tapered holding loops of the invention such as the lens shown in Fig. 3. The lenses of the present invention increase the amount of contact with the fornix area of the capsular bag by changing the bending moment along the length of the free loop portion to provide improved barrier function, vitreous support and anti-decentration characteristics of the lens implant within the eye.

As used herein, the term "optic" refers to the central optical portion of the intraocular lens. The

optic may be generally circular or elliptical, and will generally have a minimum diameter of about 4 to 5 mm to ensure complete coverage of the pupillary opening even at maximum dilation. Preferred optics are circular
5 optics having a diameter of 5.00 to 7.5 mm and elliptical optics having major axes of from 5.5 to 7.0 mm and minor axes of from 4.5 to 6.5. In addition the optic may be of various geometries such as the planoconvex, biconvex and meniscus geometries commonly
10 employed in IOLs.

Surrounding the optic, the lenses of the invention have two substantially similar holding loops, substantially symmetrically disposed about the optic. The holding loops may lie in the same plane as the lens,
15 or they may be angled at up to about twenty degrees (20°) in order to cause the lens to vault posteriorly. The holding loops may be identical (as shown in Fig. 4) or they may differ from one another, for example by the addition of manipulation aids such as positioning holes
20 or notches. Nevertheless it is important that the bending characteristics of the two loops are sufficiently similar to produce a symmetrical shape or substantially symmetrical shape when compressed in the

posterior chamber of the eye.

25 The optic and holding loops are advantageously integrally formed as a single piece from a biocompatible material. Polymethylmethacrylate (PMMA) is currently the preferred material used in making one piece lenses, and is the preferred material for lenses of the
30 invention. Oriented PMMA (Pharmacia CMTM) which exhibits increased flexibility may also be employed.

In the lenses of the invention, each holding loop may consist of just a free loop portion which is contiguous with the optic, or the holding loops may be
35 made up of two parts: a fixed gusset or flange portion

and a free loop portion. In the latter case, the gusset is a transition region between the optic and the proximal end of the free loop portion and can have various dimensions and characteristics. For example, 5 the gusset may be a clearly defined region which is separated from the optic by a bend, as depicted in Fig. 4. A gusset-like extension of the optic may also be employed such that the optic appears to have an irregular shape as in the lens shown in Fig. 5.

10 The free loop portion is an elongated flexible member. In totally encircling loop lenses, the free loop portion generally extends for about 150° or more of arc in the uncompressed state so that when compressed some part of each free loop portion lies radially 15 outward of every point of the optic periphery when viewed from above the plane of the lens optic. Of course, this appearance of a flat ring may be deceptive when the holding loops are angled relative to the lens as is frequently the case, but the absence of planarity 20 does not negative the existence of an encircling ring or the benefits achieved thereby. Preferably each free loop portion extends for about 180° of arc in the uncompressed state.

The length and shape of the free loop portion is 25 variable and depends, inter alia, on the shape of the optic. In general, the curvature of the free loop portion is such that it will follow the outer edge of the optic for a distance, after which the distance between the free loop portion and the edge of the optic 30 begins to increase, either due to a change in the curvature of the free loop portion (as in the lens shown in Fig. 1), or due to a change in the shape of the optic edge (as shown in Fig. 4) or a combination of the two. Finally, the curvature of the free loop portion 35 generally increases to give an overall shape known in the

art as a C-loop, a J-loop or a D-loop or modifications of these holding loop configurations.

In accordance with the invention, the radial thickness of the free loop portion, i.e., the thickness
5 seen when the lens is viewed from above, has a minimum value at a point or points selected to bring about improved contact between the free loop portion and the fornix or interior periphery of the capsular bag. In most cases, this can be achieved by forming a point of
10 minimum thickness within the segment of the free loop portion where the distance between it and the optic is increasing. The precise point which achieves the largest area of contact between free loop portion and fornix and thus the best results, will depend on the
15 extent to which the curvature increases toward the free or distal-end (remote from the optic) of the free loop portion and the length of the free loop portion.

The free loop portion will preferably have an radial thickness at the gusset-end and the distal end of
20 from .22 mm to .17 mm, respectively. The radial thickness at the minimum point must be sufficiently different from these thickness to alter the bending characteristics of the free loop portion in the desired manner; but cannot be so thin that the free loop portion
25 becomes unacceptably fragile. Suitable minimum thickness are from about .12 mm to about .14 mm.

Fig. 4 shows an embodiment of the invention in its uncompressed state. In Fig. 4, a 5 mm x 6 mm elliptical biconvex optic 1 is surrounded by two similar holding
30 loops 2, 2'. These holding loops have a gusset portion 3, 3' and free loop portion portions 4, 4' and are connected to the optic 1 at a 10° angle. Positioning holes 5, 5' are formed in the gusset portions 3, 3' as manipulation aids.

35 The free loop portions 4, 4' have an initial

thickness of 0.22 mm and taper to a minimum thickness of 0.14 mm at approximately in the middle of the free loop portion. The free loop portion then increases to a thickness of 0.17 mm which remains constant until the formation of a thickened tip on the distal end of the free loop portion.

Fig. 5 shows a further embodiment of the invention in which the optic 1 has an irregular shape due to the absence of a defined gusset member. One free loop portion 4 includes a positioning hole 6 near the distal end. The location of minimum thickness on each free loop portion is indicated by the arrows.

Fig. 6 shows another embodiment of the invention, in this case including a positioning notch 7 on one holding loop. The region of minimum thickness of the holding loops is again indicated by arrows.

Fig. 7, 8, 9 and 10 show further embodiments of lenses in accordance with the invention. In each case, the region of minimum thickness of the holding loops is indicated by the arrows.

The foregoing examples describe the basic concept of the present invention which is to improve contact of the holding loops with the posterior chamber structure by selectively tapering the holding loops to effect changes in bending moment at the point(s) of reduced thickness of the free loop portions. It will be understood from the examples shown and the discussion that the precise position of the region of minimum thickness will depend on the bending moment of the holding loops. It will be understood further that this inventive concept is in no way diminished by the addition of laser ridges, positioning aids or other modification for purposes other than controlling the bending characteristics of the holding loops.

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I CLAIM

1. An intraocular lens for insertion in the posterior chamber of a human following removal of a cataract comprising
- 5 (a) an optic; and
- (b) first and second similar holding loops generally symmetrically disposed about the optic, said holding loops each comprising a free loop portion which
- 10 when compressed in the posterior chamber together form a substantially encircling ring around the optic, wherein the free loop portions are tapered to a minimum radial thickness at at least one selected point to maximize contact between the free loop portions and the interior
- 15 surface of the posterior chamber when compressed.
2. An intraocular lens according to claim 1, wherein each of said free loop portions has a first segment having curvature such that it substantially follows the
- 20 outer edge of the optic, a second segment having a curvature such that the distance between the free loop portion and the edge of the optic is greater than the distance between the optic and the first segment, and a third segment having a greater curvature than the second
- 25 segment, and wherein the point of minimum thickness is within the second segment.
3. An intraocular lens according to claim 1, wherein the holding loops meet the optic at an angle of up to
- 30 20°.
4. An intraocular lens according to claim 2, wherein the holding loops meet the optic at an angle of up to
- 35 20°.

- 10 -

5. An intraocular lens according to claim 1, wherein the free loop portions each extend through an arc of at least 150°.

5 6. An intraocular lens according to claim 5, wherein
each of said free loop portions has a first segment
having curvature such that the first segment
substantially follows the outer edge of the optic, a
second segment having a curvature such that the distance
10 between the free loop portion and the edge of the optic
is greater than said distance in the first segment, and
a third segment having a greater curvature than the
second segment, and wherein the point of minimum
thickness is within the second segment.

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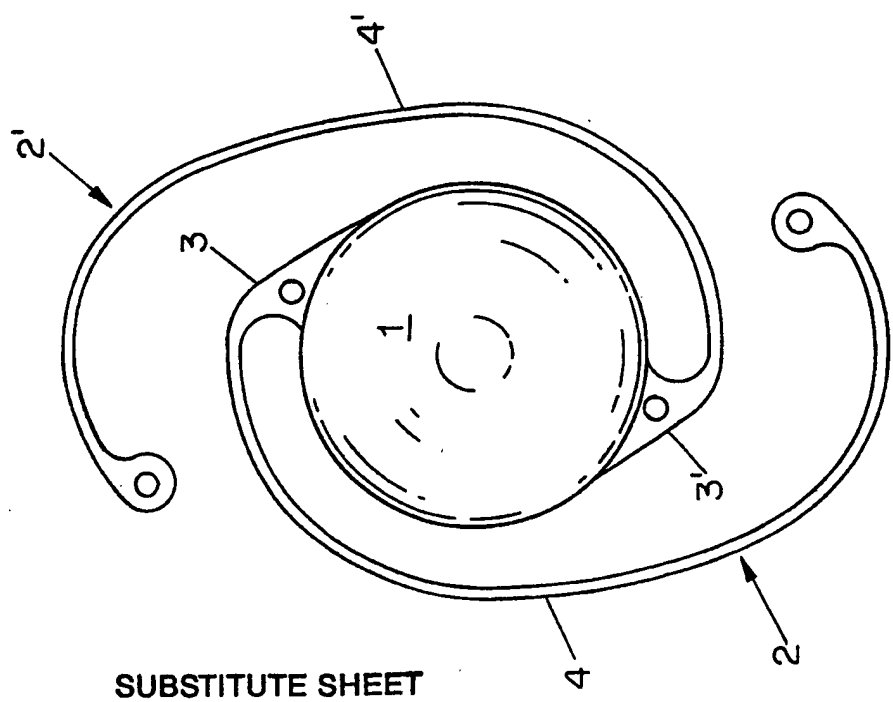
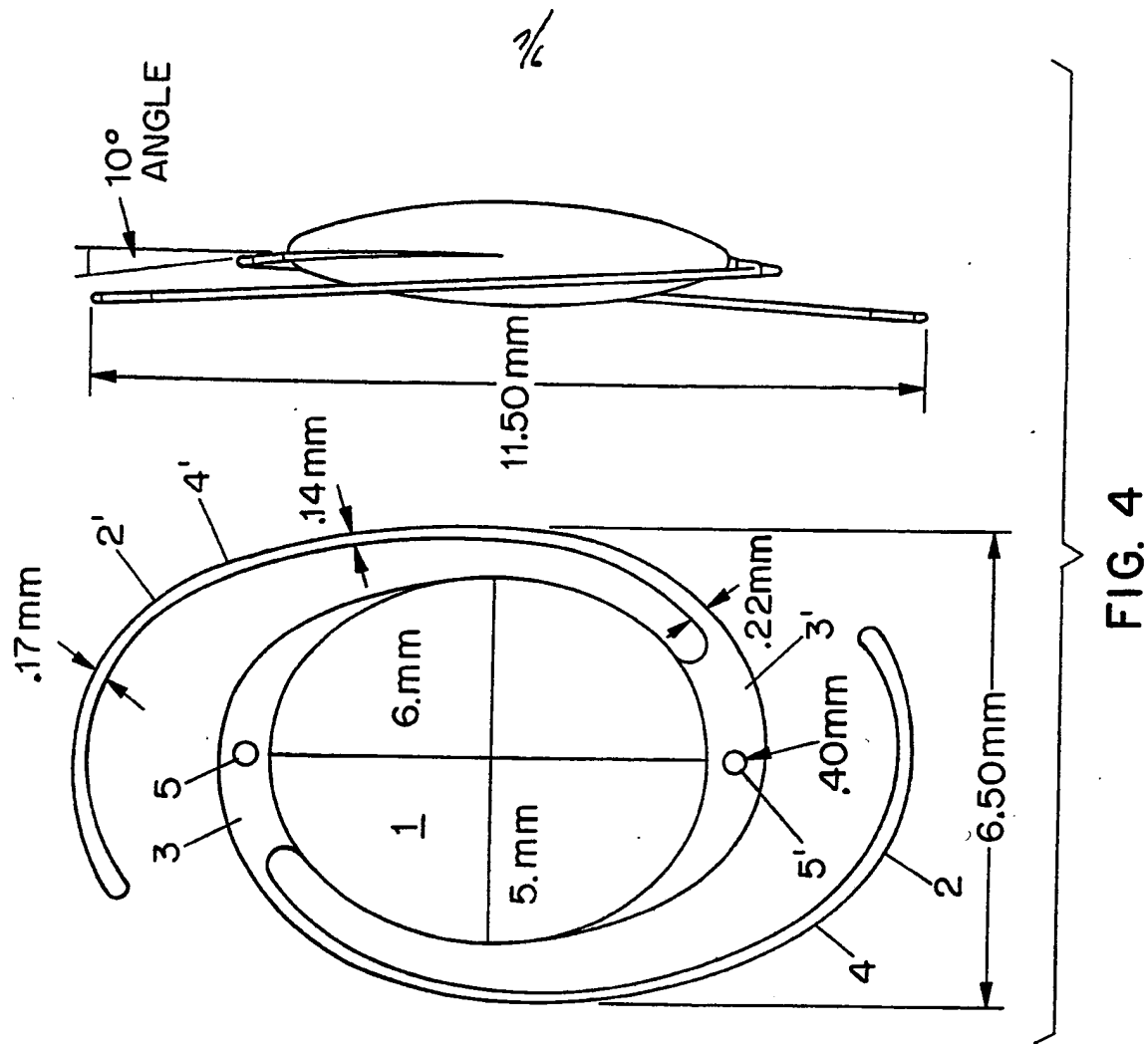


FIG. 1
PRIOR ART

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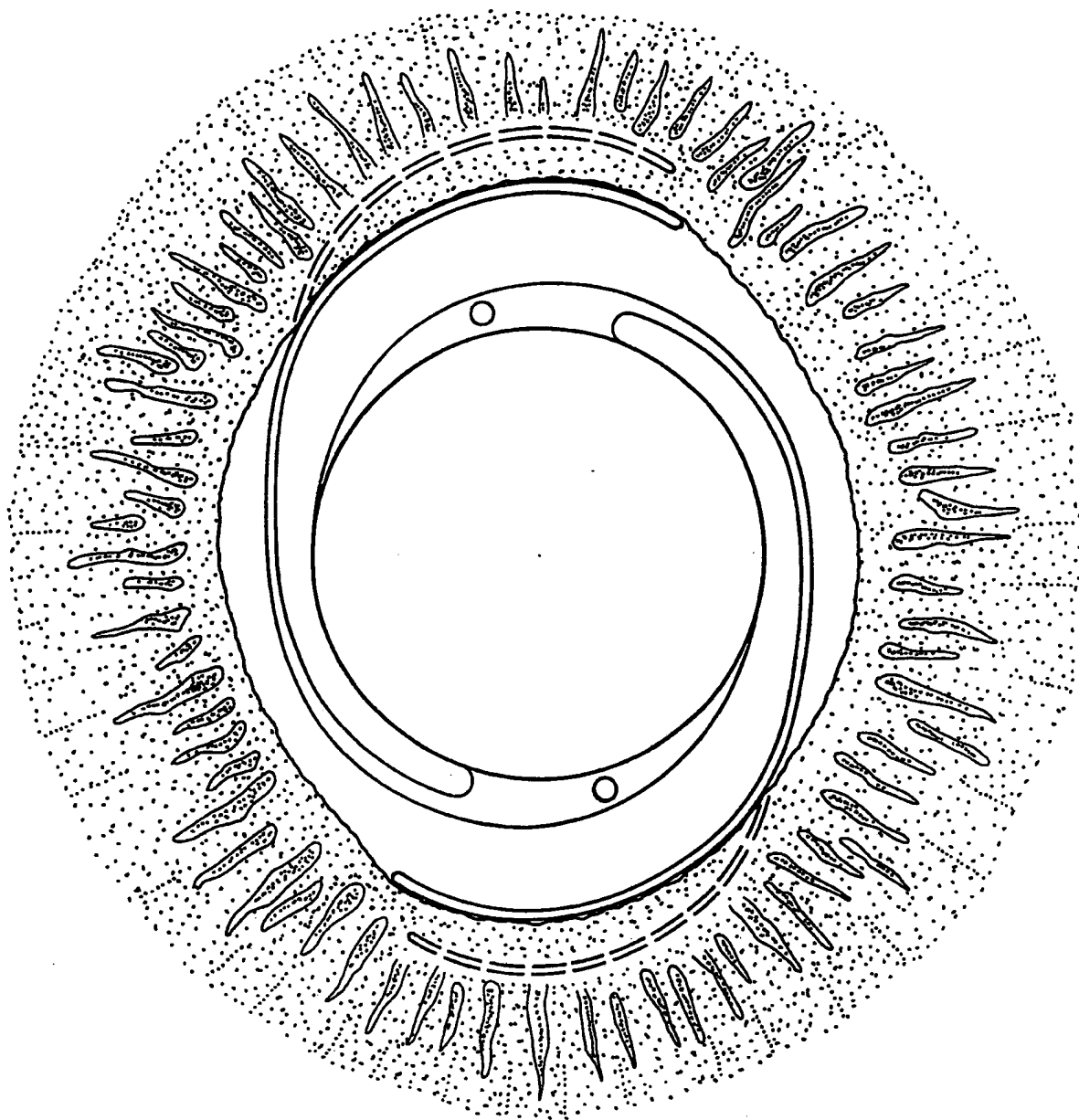


FIG. 2

SUBSTITUTE SHEET

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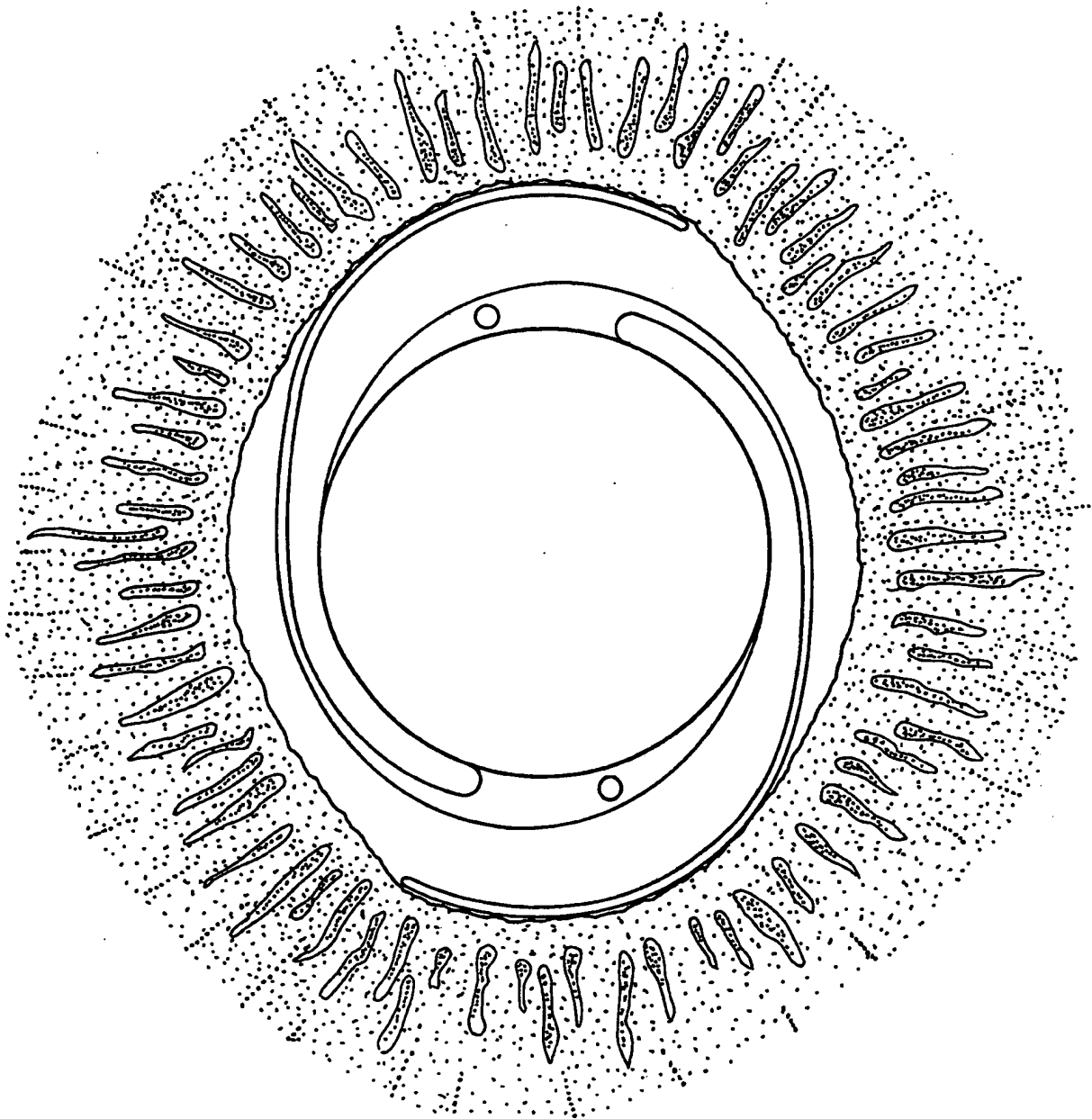


FIG. 3

SUBSTITUTE SHEET

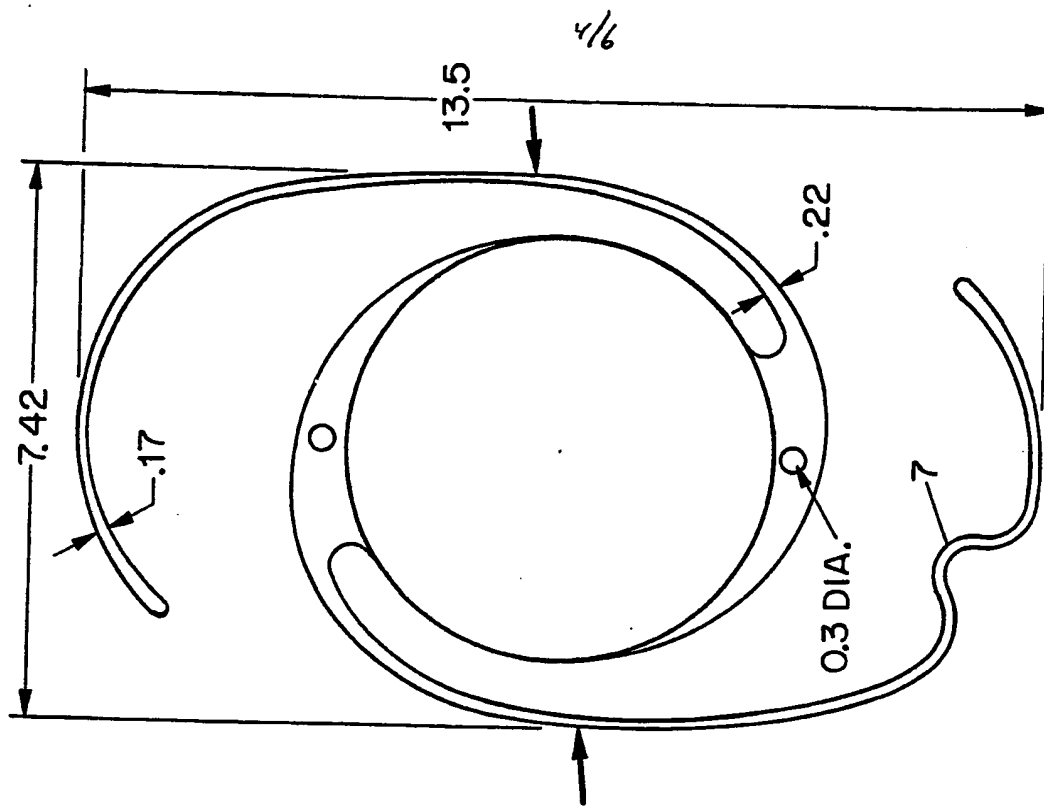


FIG. 6

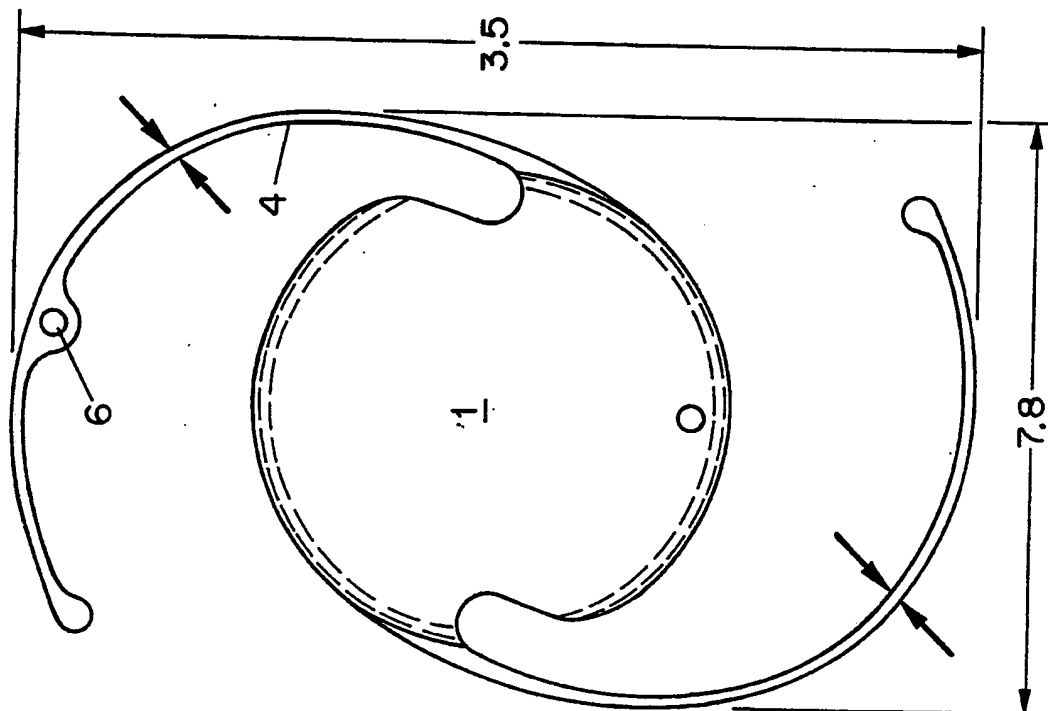


FIG. 5

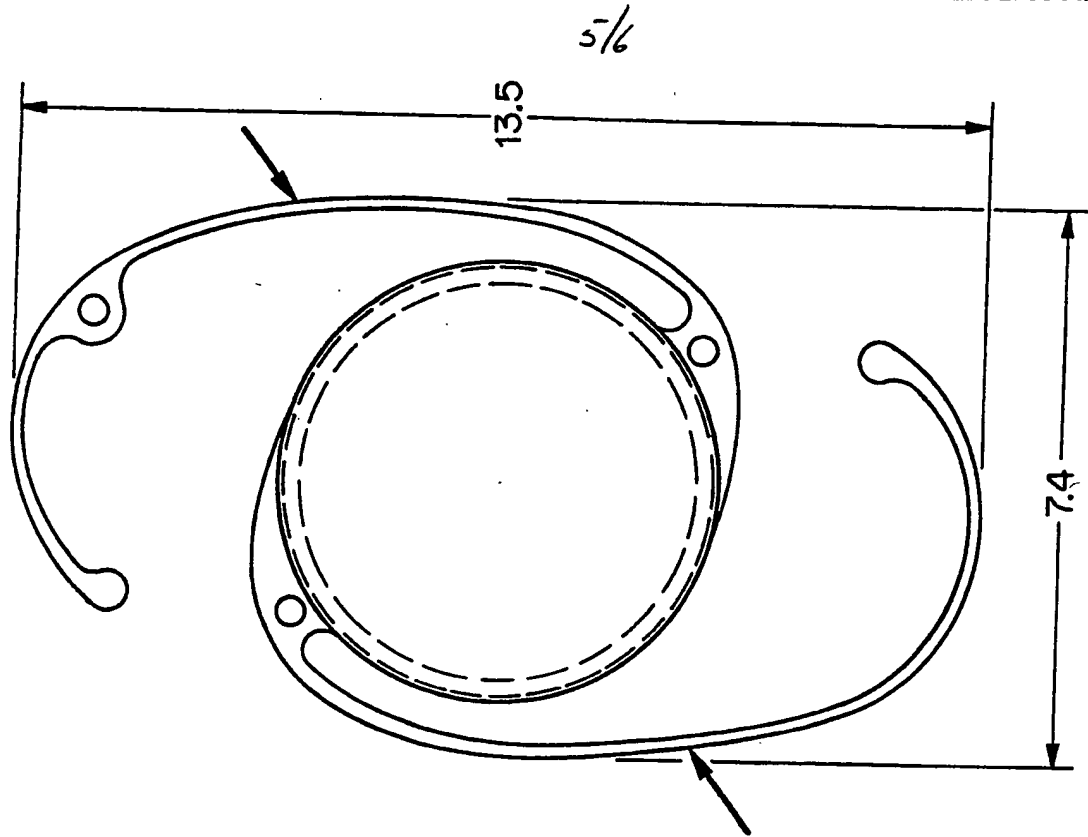


FIG. 8

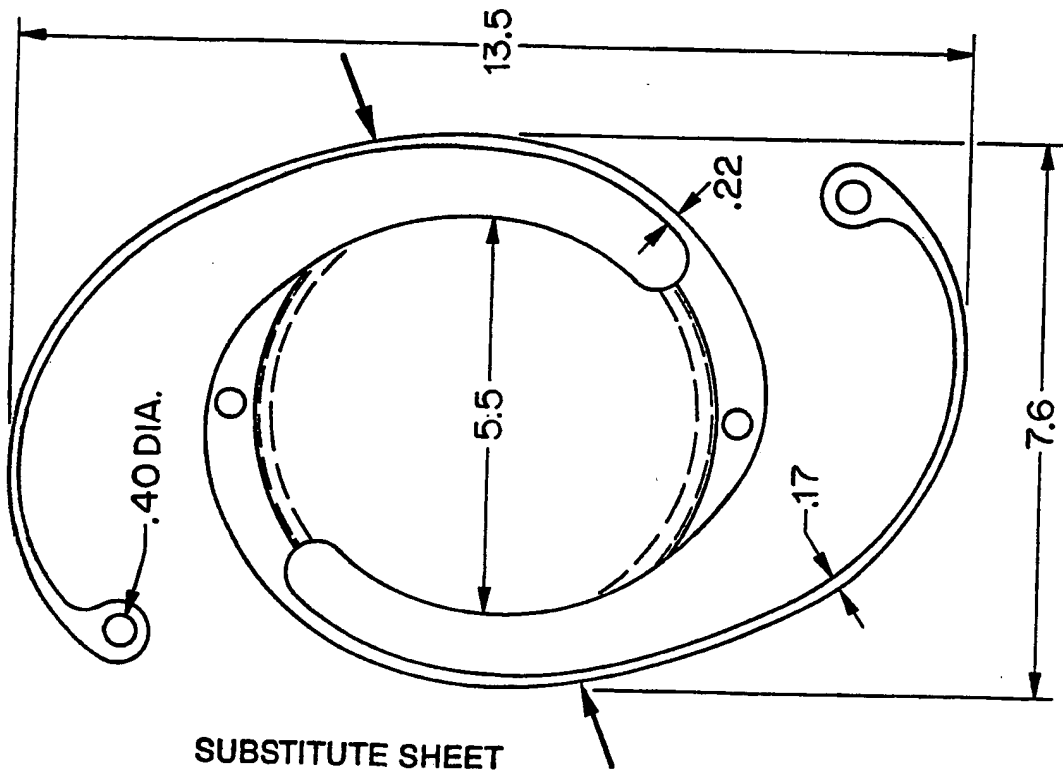


FIG. 7

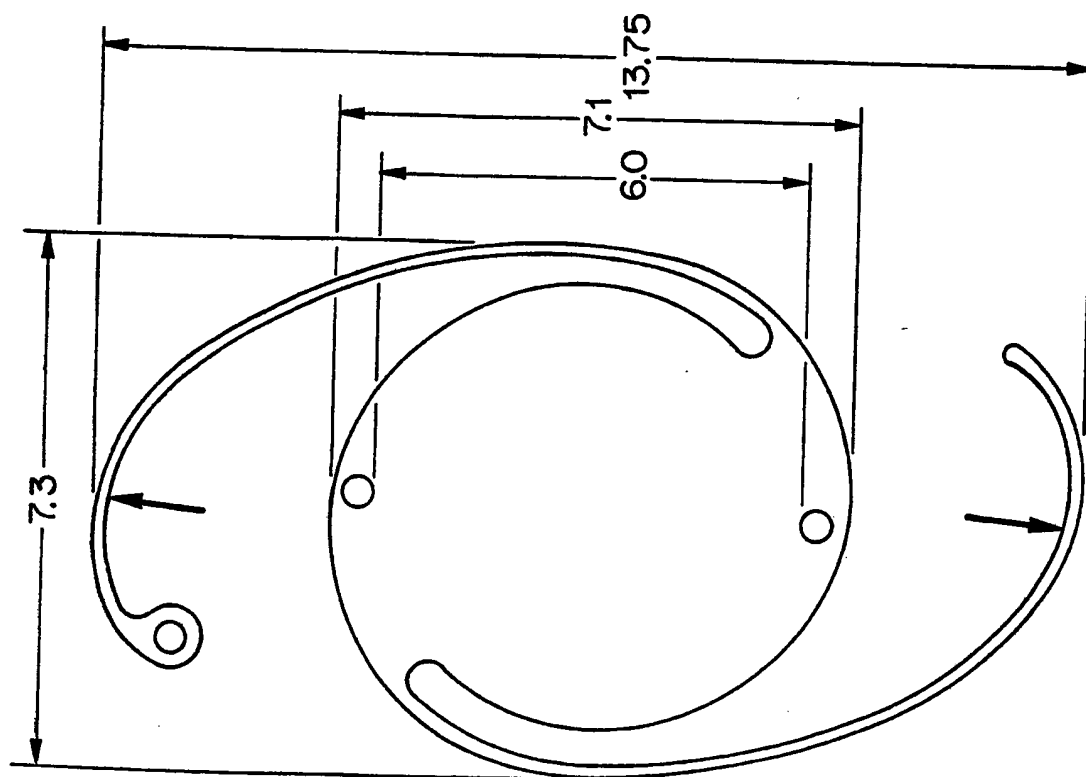


FIG. 9

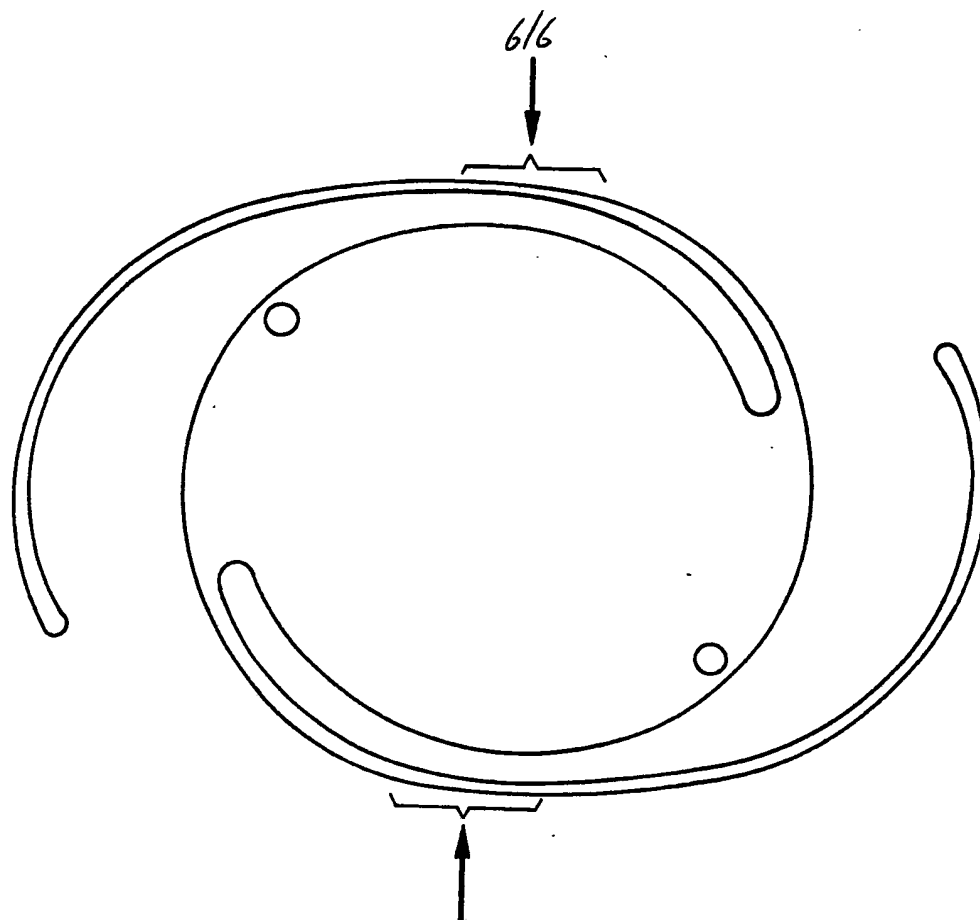


FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 92/00449

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/16

II. FIELDS SEARCHEDMinimum Documentation Searched⁷

Classification System

Classification Symbols

Int.Cl. 5

A61F

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched⁸**III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹**

Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A,4 990 159 (KRAFF) 5 February 1991 see column 6, line 47 - column 7, line 14; figures 1,2	1,3,5
Y	EP,A,0 246 216 (PRECISION-COSMET CO. INC.) 19 November 1987 see page 4, last paragraph see page 9, paragraph 2 -paragraph 3; figures 1,2,8	1-6
Y	EP,A,0 106 488 (ARNOTT) 25 April 1984 cited in the application see claims; figures	1-6
A	EP,A,0 278 724 (KELMAN) 17 August 1988 see abstract; figure 3	1,2

⁹ Special categories of cited documents: ¹⁰^{"A"} document defining the general state of the art which is not
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in the art.^{"A"} document member of the same patent family**IV. CERTIFICATION**

Date of the Actual Completion of the International Search

29 APRIL 1992

Date of Mailing of this International Search Report

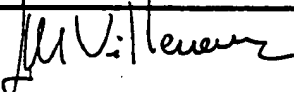
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VILLENEUVE J.M.



**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

**EP 9200449
SA 56932**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4990159	05-02-91	None		
EP-A-0246216	19-11-87	US-A- DE-A-	4725277 3772098	16-02-88 19-09-91
EP-A-0106488	25-04-84	US-A- US-E-	4476591 RE33039	16-10-84 29-08-89
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